Edan Instruments, Inc.
℅ Melody Huang
Regulatory Engineer
#15 Jinhui Road, Jinsha Community
Kengzi Sub-District, Pingshan District
Shenzhen, Guangdong 518122
P.R. CHINA

May 21, 2020

Re: K192879
Trade/Device Name: Acclarix AX8 Diagnostic Ultrasound System / Acclarix LX9 Series Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: April 17, 2020
Received: April 20, 2020

Dear Melody Huang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192879

Device Name
Acclarix AX8 Diagnostic Ultrasound System / Acclarix LX9 Series Diagnostic Ultrasound System

Indications for Use *(Describe)*

The Acclarix LX9 Series/ Acclarix AX8 Diagnostic Ultrasound System is intended for use by a qualified physician or allied health professional for ultrasound evaluation in hospitals and clinics. Clinical applications include Abdominal, Gynecology, Obstetric, Cardiac, Small parts, Urology, Musculoskeletal, Peripheral vascular, Intra-operative, Pediatric, Neonatal and Adult Cephalic.

The Modes of Operation for Acclarix LX9 series include B mode, M mode, Doppler mode, Harmonic Imaging, Elastography Imaging, Contrast imaging and their combination modes.
The Modes of Operation for Acclarix AX8 include B mode, M mode, Doppler mode, Harmonic Imaging, Elastography Imaging and their combination modes.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

K192879 **Prepared in accordance with the requirements of 21 CFR Part 807.92**

1. Submitter:	Edan Instruments, Inc. #15 Jinhui Road, Jinsha Community, Kengzi Sub-District, Pingshan District, Shenzhen, 518122 P.R.China. Tel: +86-755-2685 8736 Fax: +86-755-2689 8330
Contact person:	Melody Huang
Preparing date:	Sep. 25, 2019
2. Device name and classification:	**Device Name:** Acclarix AX8 Diagnostic Ultrasound System / Acclarix LX9 Series Diagnostic Ultrasound System **Model:** Acclarix AX8, Acclarix LX9, Acclarix LX9 Exp, Acclarix LX9 Super, Acclarix LX85, Acclarix LX88 **Classification Name/ Product code:** 21 CFR 892.1550 System, Imaging, Pulsed Doppler, Ultrasonic / IYN 21 CFR 892.1560, Ultrasonic, Pulsed echo, Imaging / IYO 21 CFR 892.1570, Transducer, Ultrasonic, Diagnostic / ITX **Regulatory Class:** Class II
3.Premarket Notification Class III Certification and Summary	Not applicable, the subject device is Class II.
4. Predicate Device(s):	1) Edan Instruments, Acclarix AX8 Diagnostic Ultrasound System, cleared under K180862 (Primary) 2) Shenzhen Mindray, DC-80 Diagnostic Ultrasound System, cleared under K173471 (Reference)
5. Reason for Submission	By submission of the Traditional 510(k), Edan Instruments is requesting clearance for an updated version of the Acclarix AX8 Diagnostic Ultrasound Systems and new models of the Acclarix LX9 series Diagnostic Ultrasound Systems.
6.Pre-Submission, IDE	Not applicable, there is no pre-submission.
7. Device Description:	Acclarix AX8/ Acclarix LX9 Series is a software controlled Diagnostic Ultrasound System, which consists of a main unit along with associated transducers. It is intended for use by a qualified physician or allied health professional for ultrasound evaluations. This system is a Track 3 device to acquire and display ultrasound data in

various imaging modes.

8. Indication for Use

The Acclarix LX9 Series/ Acclarix AX8 Diagnostic Ultrasound System is intended for use by a qualified physician or allied health professional for ultrasound evaluation in hospitals and clinics. Clinical applications include Abdominal, Gynecology, Obstetric, Cardiac, Small parts, Urology, Musculoskeletal, Peripheral vascular, Intra-operative, Pediatric, Neonatal and Adult Cephalic.

The Modes of Operation for Acclarix LX9 series include B mode, M mode, Doppler mode, Harmonic Imaging, Elastography Imaging, Contrast imaging and their combination modes.
The Modes of Operation for Acclarix AX8 include B mode, M mode, Doppler mode, Harmonic Imaging, Elastography Imaging and their combination modes.

9. Predicate Device Comparison

The subject devices Acclarix AX8 and Acclarix LX9 series have the same technological characteristics, is comparable in key safety and effectiveness features, and has the same intended uses and basic operating modes as the primary predicated device Acclarix AX8 (K180862), except the following main differences.

The main changes of the subject devices Acclarix AX8 and Acclarix LX9 series compared with the primary predicated device Acclarix AX8 (K180862) are as the followings:

1) Addition of new transducers: C7-2XQ, E10-3BQ, E10-3HQ, C5-1Q, which have similar specifications, same intended use and same modes of operation as the transducers of Acclarix AX8 (K180602).

2) Addition of Color M mode, which is substantially equivalent to that of the reference predicate device DC-80 (K173471).

3) Addition of Strain Elastography mode on Linear transducers, including L10-4Q, L12-5Q, L17-7HQ and L17-7SQ, which is substantially equivalent to that of the reference predicate device DC-80 (K173471).

4) Addition of ECG module to support ECG waveform display on the ultrasound image, which is substantially equivalent to that of the reference predicate device DC-80 (K173471). The ECG function is supported on P5-1Q transducer. The ECG function on Acclarix AX8 is provided by an external ECG module, while the ECG function on Acclarix LX9 series is provided by a built-in ECG module.

5) Addition of Auto OB and Auto NT measurement function, which is substantially equivalent to the reference predicate device DC-80 (K173471).

The additional changes of the subject device Acclarix LX9 series compared with primary predicated device Acclarix AX8 (K180862) are as the followings:

1) Acclarix LX9 series additionally supports a transducer C6-2MQ for 3D/4D imaging. 3D/4D imaging is not a new feature for EDAN device which was cleared in transducer C5-2MQ of Acclarix AX8 (K180602).

2) Acclarix LX9 series does not support C5-2XQ, L10-4Q, P5-1XQ and C5-2MQ transducers, which were cleared in Acclarix AX8 (K180862).

3) Acclarix LX9 series additionally supports Contrast Imaging mode for Liver on C5-1Q and C5-2Q transducers, and the Contrast Imaging mode is substantially equivalent to the reference predicate device DC-80 (K173471).

The subject and predicate devices have similar design features and performance specifications. The technological differences between the subject and predicate devices do not raise different questions of safety or effectiveness.

10. Performance Data:

Clinical test:

Clinical testing is not required.

Non-clinical test:

The Acclarix AX8/ Acclarix LX9 series Diagnostic Ultrasound Systems comply with:

(1) ANSI AAMI ES60601-1 Electrical Safety

(2) IEC 60601-1-2 Electromagnetic Compatibility

(3) IEC 60601-2-37 Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment

(4) Guidance for Industry and FDA Staff—Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers issued on June 27, 2019

(5) IEC 62359 Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields

The following biocompatibility standards are conducted on the subject device:

(1) ISO 10993-1, ISO 10993-5, ISO 10993-10, ISO 10993-12

The tests were selected to show substantial equivalence between the subject devices and the predicate devices.

The non-clinical performance testing showed that the subject devices are as safe and as effective as the predicate devices.

11. Conclusion

Verification and validation testing has been conducted on the Acclarix AX8/ Acclarix LX9 Series Diagnostic Ultrasound Systems. This premarket notification submission demonstrates that Acclarix AX8/ Acclarix LX9 Series

Diagnostic Ultrasound Systems are substantially equivalent to the predicate devices.